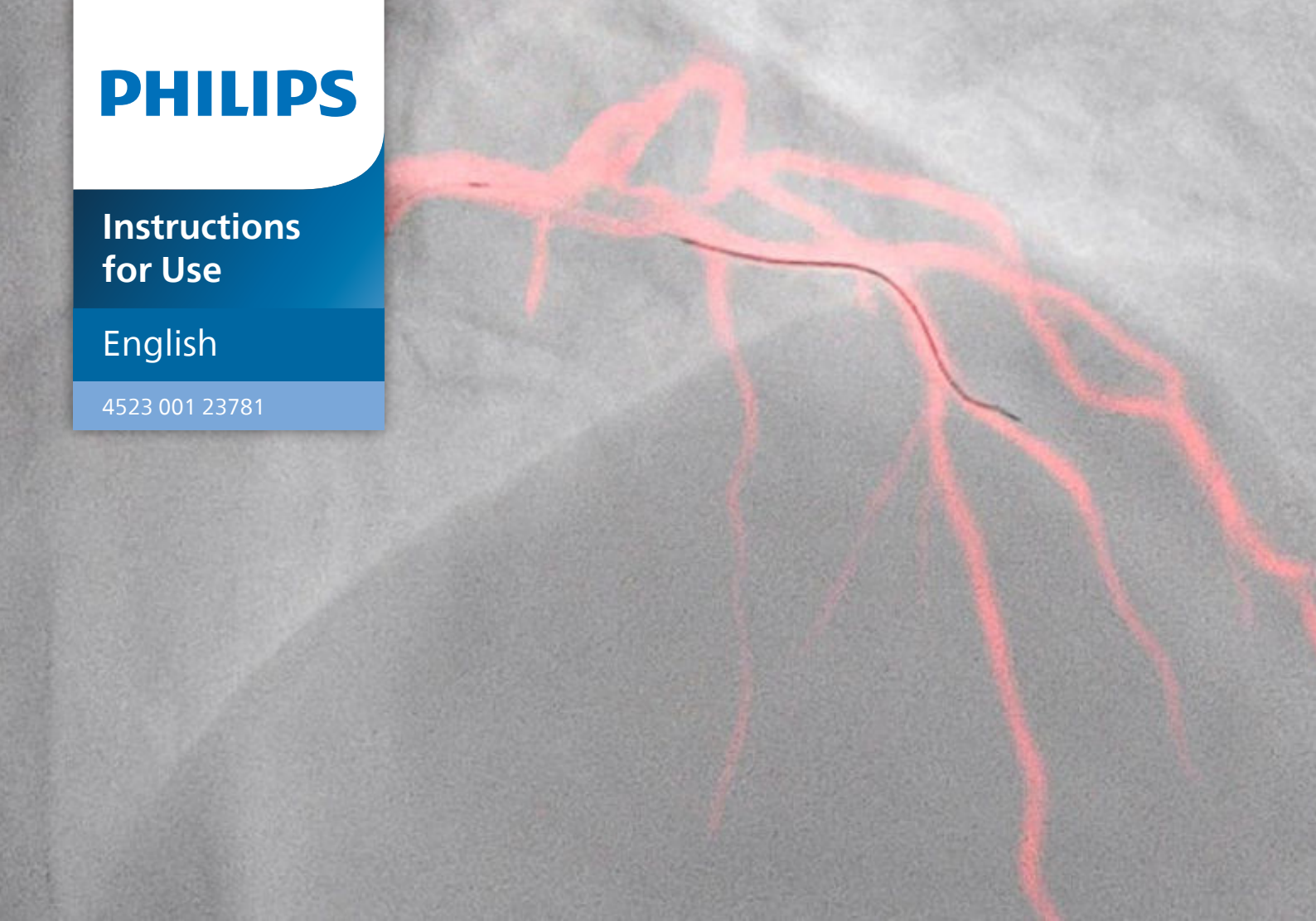




PHILIPS

**Instructions
for Use**

English

4523 001 23781

Philips Dynamic Coronary Roadmap

Release 3.1

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1 Introduction

About Dynamic Coronary Roadmap

Dynamic Coronary Roadmap is a software medical device that provides a real-time, dynamic angiographic roadmap of coronary arteries. Dynamic Coronary Roadmap is used in combination with a Philips interventional X-ray system.

The angiographic roadmap is automatically generated from diagnostic coronary angiograms acquired during the same procedure.

The angiographic roadmap is overlaid on live 2D fluoroscopy images, assisting you with navigating devices such as guide wires and catheters, through the coronary arteries.

When used with a compatible Philips intravascular blood pressure measurement system (optional), which measures intravascular blood pressure values, Dynamic Coronary Roadmap provides FFR/iFR Roadmap for Fractional Flow Reserve (FFR) or instant wave-Free Ratio (iFR) measurements. This feature combines blood pressure information in a coronary artery with an X-ray image of the pressure wire in the same coronary artery, acquired when the pressure measurement was performed.

1.1 About these Instructions for Use

These Instructions for Use are intended to assist operators in the safe and effective operation of the product described. The "responsible organization" is considered to be the body with authority over the product and "operators" are those persons who actually use the product.

To identify the Instructions for Use and the software tool for which they are intended to be used, the product can be identified using the **About** box of the related software tool. The **About** box indicates the following:

- Name of the product
- Release number
- Date of manufacture
- Unique device identifier (UDI)

All Instructions for Use supplied with the software tool are identified using the name and release number (first two digits) of the software tool, as indicated in the footer of the document. Before using these Instructions for Use with your system, ensure that it corresponds with the software tool installed.

These Instructions for Use may describe some products or features that are not available in all countries. Please contact your local sales representative for the availability of products and features in your region.

These Instructions for Use describe the most extensive configuration of Dynamic Coronary Roadmap, including any options that may be available. Depending on the configuration of your system, some of the features described may not be available.

Before attempting to operate the product, you must read these Instructions for Use, noting and strictly observing all **WARNING** and **CAUTION** notices.

Pay special attention to all the information given and procedures described in the Safety section.



WARNING

A warning alerts you to a potential serious outcome, adverse event, or safety hazard. Failure to observe a warning may result in death or serious injury to the operator or patient.



CAUTION

A caution alerts you when special care is necessary for the safe and effective use of the system. Failure to observe a caution may result in moderate injury to the operator or patient, or damage to the equipment, and presents a remote risk of more serious injury or environmental pollution.

NOTE

A note highlights unusual points to assist you when using the system.

Information about the acquisition of images with the correct protocol is contained in the relevant Instructions for Use of the compatible X-ray equipment. The operator is expected to have received training for the correct operation of the X-ray equipment.

1.2 Intended Use

This Philips product is intended to be installed, used, and operated only in accordance with the safety procedures and operating instructions given in these Instructions for Use for the purposes for which it was designed.

The purposes for which the product is intended are given below. However, nothing stated in these Instructions for Use reduces operators' responsibilities for sound clinical judgment and best clinical procedure.

Installation, use, and operation of this product are subject to the law in the jurisdictions in which the product is being used. Operators must only operate the product in such a way as to not conflict with applicable laws, or regulations that have the force of law.

Uses of the product for purposes other than those intended and expressly stated by Philips, as well as incorrect use or operation, may relieve Philips (or its agent) from all or some responsibility for resultant non-compliance, damage, or injury.



CAUTION

In the United States, Federal law restricts this device to sale, distribution, and use by, or on the order of, a physician.

1.2.1 Intended Use of Dynamic Coronary Roadmap

Product Description

Dynamic Coronary Roadmap is a software medical device intended to provide a real-time and dynamic angiographic roadmap of coronary arteries.

The angiographic roadmap is automatically generated from previously acquired diagnostic coronary angiograms during the same procedure.

Dynamic Coronary Roadmap overlays the angiographic roadmap on live 2D fluoroscopic images, thereby assisting the physician in navigating devices, e.g. (guide) wires, catheters, through the coronary arteries.

Dynamic Coronary Roadmap is to be used in combination with a Philips interventional X-ray system.

When also used in conjunction with a compatible intravascular blood pressure measurement system, Dynamic Coronary Roadmap offers an FFR/iFR Roadmap feature which combines the information of the blood pressure within a coronary artery with an X-ray image of the pressure wire within that coronary artery, acquired when the pressure measurement was performed.

Indications for Use / Medical Purpose

Dynamic Coronary Roadmap is intended to assist the physician during percutaneous coronary interventions in correlating the device position to the coronary vasculature, by providing a motion compensated overlay of this coronary vasculature.

The FFR/iFR Roadmap feature is intended to assist the physician during percutaneous coronary interventions in relating the intravascular blood pressure measurement to its anatomical location. FFR/iFR roadmap visualizes the position of the pressure wire and the coronary artery on an X-ray image at the moment that an intravascular blood pressure measurement was performed as well as the intravascular blood pressure measurement values themselves.

Dynamic Coronary Roadmap is suitable for use with the entire adult human population.

Intended Operator Profile

Dynamic Coronary Roadmap is intended to be used and operated by: adequately trained, qualified, and authorized healthcare professionals who have understanding of the safety information and emergency procedures as defined by local laws and regulations for radiation workers and staff.

Clinical environment

Dynamic Coronary Roadmap is intended to be used in the cath lab, interventional suite or hybrid operating room. The software medical device is connected to a Philips interventional X-ray system. Additionally it may also be connected to a compatible intravascular blood pressure measurement system.

General safety and effectiveness

To facilitate safe and effective operation of the system by a trained healthcare professional, instructions for use are provided as part of the device labeling.

Dynamic Coronary Roadmap is a software medical device and does not come in contact with a human subject.

Contraindications

The images made with the product use X-ray imaging as the source data, obtained from compatible X-ray equipment. All contraindications that apply for X-ray procedures described in the Instructions for Use for the compatible X-ray equipment also apply for the procedures mentioned in these Instructions for Use.

Operating principle

The software medical device uses X-ray generated data as input data and image processing for medical imaging and/or pressure data from a compatible intravascular blood pressure measurement system. The software medical device provides visual feedback.

1.3 Compatibility

Dynamic Coronary Roadmap Release 3.1 is intended to be used in combination with the following systems:

- Allura Release 8.x.17.2
- Allura Release 8.x.30.5 (or higher)
- UNIQ/UNIQ Clarity Release 1.0.2
- UNIQ/UNIQ Clarity Release 1.0.30.5 (or higher)
- Azurion Release 1.1.1
- Azurion Release 1.1.5
- Azurion Release 1.2.1 (or higher)
- Azurion Release 2.x
- Azurion Release 3.x

Dynamic Coronary Roadmap Release 3.1 is compatible with the following intravascular blood pressure measurement systems:

- Volcano CORE Integrated, containing FM (functional measurement) software Release 2.5
- Volcano CORE Mobile, containing FM (functional measurement) software Release 2.5
- Philips IntraSight Integrated Release 1.0
- Philips IntraSight Integrated Release 1.1

NOTE

For details of compatible systems in China, contact Philips.

The product described in this manual should not be used in combination with other products or components unless such other products or components are expressly recognized as compatible by Philips. A list of such products and components is available on request. For contact details, see [Contacting Philips \(page 8\)](#).

Changes or additions to the product should only be carried out by Philips or by third parties expressly authorized by Philips to do so. Such changes or additions must comply with all applicable laws and regulations that have the force of law within the jurisdictions concerned, and with best engineering practice.

Dynamic Coronary Roadmap is only intended to be used with the PC hardware configuration on which it is initially installed by Philips. Dynamic Coronary Roadmap may only be installed or reinstalled by authorized service personnel.

1.4 Compliance

This product complies with relevant international and national standards and laws. Information on compliance will be supplied on request by your local Philips representative.

1.5 Training

Do not attempt to operate this product without adequate training. As a minimum level of training, you should read and understand these Instructions for Use.

Application training is also available. For more information about the availability of application training, including information on the duration and frequency of training, contact Philips. See [Contacting Philips \(page 8\)](#).

1.6 Third-Party Software

This product uses other software, including open-source software. Details of this software can be found in the following location on the installation medium:

OpenSource\OpenSource_DynamicCoronaryRoadmap.zip

1.7 Contacting Philips

You can contact Philips by post or using the Philips website.

Contact details	
Postal address	Philips Medical Systems Nederland B.V. Veenpluis 6 5684 PC Best The Netherlands
Website address	www.philips.com/healthcare

2 Safety

All Philips products are designed to meet stringent safety standards. To safeguard human safety all medical device software requires proper installation, use, and maintenance.

It is vital that you read, note, and where applicable, strictly observe all **DANGER** notices and safety markings on the outside of the IT equipment on which the medical device software has been installed.

To help ensure the safety of both patients and operators, it is vital that you strictly follow all directions under the heading Safety and all **WARNINGS** and **CAUTIONS** given throughout these Instructions for Use or displayed on the user interface.

Only qualified and authorized personnel may operate this product. In this context, qualified means those legally permitted to operate this type of medical electrical product in the jurisdictions in which the product is being used, and authorized means those authorized by the user of the product.

Personnel operating the product and personnel in the examination room must observe all laws and regulations which have the force of law within the jurisdictions concerned. If you are in any doubt about the laws and regulations which apply to the operation of this product, do not use it.

Emergency Procedures

Due to the nature of this product, there are no emergency procedures. For information about emergency procedures related to the X-ray equipment, refer to the Instructions for Use supplied with the X-ray system.

Radiation Safety

For information about radiation safety refer to the **Safety** section of the Instructions for Use supplied with the X-ray system.

Side Effects

Dynamic Coronary Roadmap has no known side effects.

Product Symbols

For information about the symbols that are used with this product, refer to the following website:

www.symbols.philips.com

2.1 Reporting a Serious Incident

If a serious incident occurs in relation to the device, it should be reported to Philips and the competent authority of the country where you are located.

A serious incident means any incident that directly or indirectly led to, might have led to, or in case of recurrence, could lead to, any of the following:

- The death of a patient, user, or other person.
- The serious deterioration of the state of health (temporary or permanent) of a patient, user, fetus, or other person.
- A serious public health threat.

For contact details, see [Contacting Philips \(page 8\)](#).

2.2 Safety Guidance for Using Dynamic Coronary Roadmap



CAUTION

Ensure that the following conditions are met during acquisition of the roadmap:

- *Ensure that you use the same catheter during live guidance that you used to create the roadmap.*
- *Ensure that the catheter tip is always visible.*
- *Instruct the patient to remain still.*
- *Do not move the stand or table.*
- *Acquire at least three contrast-enhanced heart cycles.*

NOTE

If there are other objects in the field of view, such as stitches, stents, or a pacemaker, the resulting roadmap may not be optimal.

NOTE

If similar anatomy is present in the region of interest (for example, parallel vessels), the resulting roadmap may not be suitable for live guidance due to unreliable spatial registration.

NOTE

The full coronary tree should be filled with contrast for at least three heart cycles. In case of chronic total occlusions, not all vessels might be filled with contrast agent. These vessels are not visible in the roadmap, or the roadmap itself might not be available.

NOTE

Depending on the anatomy, the quality of a roadmap may not be sufficient for device navigation. Always ensure that the selected roadmap is of sufficient quality by comparing the roadmap to the original angiogram.

NOTE

Autonomous patient movement or anatomy deformation due to device insertion may result in an incorrect overlay. If device navigation is hindered by an incorrect overlay, create a new roadmap. Alternatively, use the information from the live screen of the X-ray system and small puffs of contrast to assist with device navigation.

2.3 Performance

The performance of Dynamic Coronary Roadmap has been verified and validated by indirect assessment. During verification performance testing of 12,966 individual images using pass/fail criteria, Dynamic Coronary Roadmap provided correct overlay in 96.9% of the cases. During validation testing 89% of 127 samples were confirmed as providing navigational support during PCI by interventional cardiologists.

If the Dynamic Coronary Roadmap workstation is switched on and off automatically with the X-ray system, Dynamic Coronary Roadmap shall be ready for clinical use within 5 minutes after pressing the **Power On** button on the X-ray system. For more information, see [Switching On and Off \(page 12\)](#).

Dynamic Coronary Roadmap shall create a 2D dynamic roadmap within 10 seconds after the 2D coronary angiographic exposure run is acquired.

During live guidance, Dynamic Coronary Roadmap shall blend the 2D dynamic roadmap with the live X-ray images such that the 2D dynamic roadmap and the devices used to perform the intervention can be distinguished from each other.

2.4 Symbols

The following symbols may be used on the device, its packaging, or any other related materials.

Symbol	Description
	Manufacturer This symbol indicates the manufacturer of the medical device or accessory. The date of manufacture may also be displayed with this symbol, displayed as four digits for the year and, where appropriate, two digits for the month and two digits for the day.
	Date of Manufacture This symbol indicates the date when the medical device was manufactured. The date of manufacture is displayed as four digits for the year and, where appropriate, two digits for the month and two digits for the day. It is displayed on the system label.
	Batch Code This symbol indicates the manufacturer's batch code so that the batch or lot can be identified.
	Unique Device Identifier This symbol indicates a carrier that contains unique device identifier information.
	Medical Device This symbol indicates that the item is a medical device.
	Model Number This symbol indicates the model number or type number of the product.
	European Conformity This symbol indicates that the equipment complies with applicable European directives and regulations. The number of the notified body is indicated, if applicable.
	Prescription Device In the United States, Federal law restricts this device to sale by or on the order of a physician.
	Consult the Instructions for Use This symbol indicates the need for the user to consult the Instructions for Use.
	Caution This symbol indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action to avoid undesirable consequences.
	Authorized Representative This symbol indicates the authorized representative in the region indicated by XX.
	UK Conformity Assessed This symbol indicates that the equipment complies with applicable regulations in the United Kingdom. The number of the notified body is indicated, if applicable.

3 Switching On and Off

Depending on the configuration of systems at your site, the workstation is switched on either automatically or manually.

If the Dynamic Coronary Roadmap workstation is located in the technical room, it is switched on and off automatically with the X-ray system. For more information, see [Switching On and Off Automatically \(page 12\)](#).

If the Dynamic Coronary Roadmap workstation is located in the control room, you have to switch it on and off manually. For more information, see [Switching On and Off Manually \(page 12\)](#).

3.1 Switching On and Off Automatically

If the Dynamic Coronary Roadmap workstation is located in the technical room, it switches on and off automatically with the X-ray system, no other actions are needed.

NOTE

If the Dynamic Coronary Roadmap window remains blank, restart the X-ray system.

3.2 Switching On and Off Manually

If the Dynamic Coronary Roadmap workstation is located in the control room, you have to switch it on and off manually.

NOTE

Do not switch off the workstation using the power switch while Dynamic Coronary Roadmap is still running, as this may damage data integrity. Close Dynamic Coronary Roadmap using the procedure described here before switching off the workstation.

- 1 To start Dynamic Coronary Roadmap, press the power switch on the Dynamic Coronary Roadmap workstation in the control room.
- 2 To shut down Dynamic Coronary Roadmap, do the following:
 - a In the **System** menu of Dynamic Coronary Roadmap, click **Philips SupportConnect**.

NOTE

If you attempt to start Philips SupportConnect while a DICOM transfer task is in progress, an on-screen message is displayed, recommending that you wait for the transfer to finish before starting Philips SupportConnect. If you start Philips SupportConnect before the transfer finishes, any snapshots or movies that are not yet transferred will be lost. Click Close (X) in the upper-right corner of the message box, wait for the transfer to finish, and then start Philips SupportConnect.



- b In the Philips SupportConnect application, click **Power Off** in the lower-right corner and then confirm your action.

4 Operation

4.1 Dynamic Coronary Roadmap Window Overview

Before you create a roadmap, the main view of Dynamic Coronary Roadmap displays guidance messages to assist you with the process. When you have created a roadmap and you start live guidance, the main view displays live fluoroscopy images overlaid with the roadmap.

NOTE
Dynamic Coronary Roadmap provides additional image information. It does not replace the live image viewer of the X-ray system.

If a compatible Philips intravascular blood pressure measurement system is used in combination with Dynamic Coronary Roadmap (optional), the iFR or FFR values are visible as long as the pressure wire is connected and the same acquisition protocol remains active.

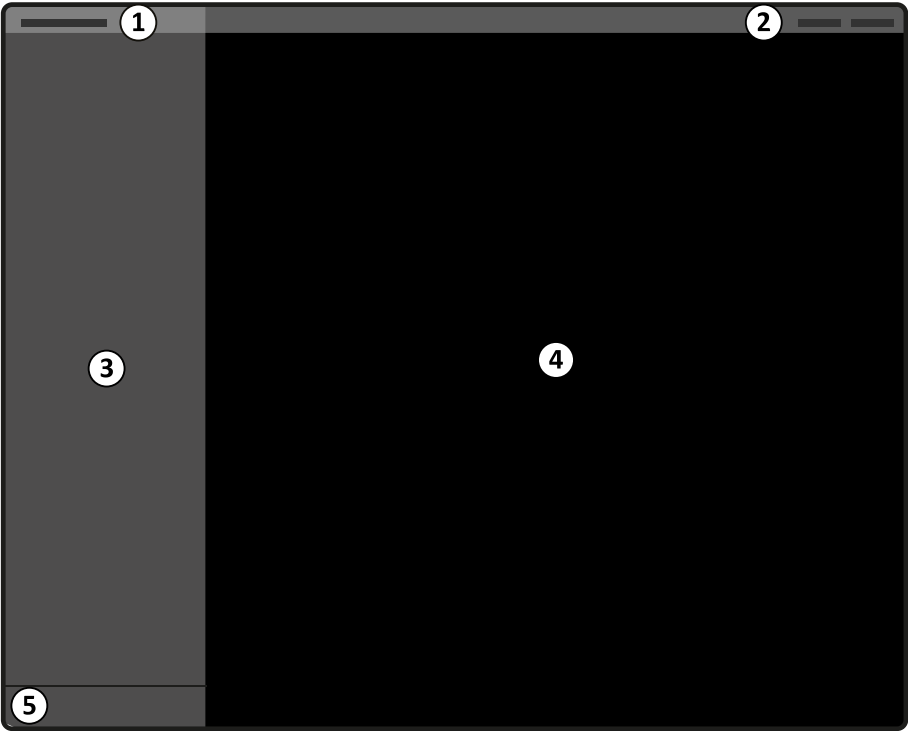


Figure 1 Dynamic Coronary Roadmap window overview

Legend			
1	Patient name, as selected on the X-ray system	4	Main view This view displays the following: • Guidance messages for using the application • Live fluoroscopy images overlaid with the roadmap during live guidance
2	Menus, providing access to technical support options and information about the system	5	Status indicators for the connection to the Philips intravascular blood pressure measurement system (optional)
3	Reference view This view displays iFR or FFR measurements (optional)		

Reference View
Depending on the configuration of your system, the reference view and status indicators may appear on the left side or the right side of the main view, or in a dedicated window beside the main view.



Figure 2 The location of the reference view and status indicators depends on the configuration of your system

4.2 Snapshots and Movies

You can create DICOM-compatible snapshots and movies during an intervention using the touch screen module. Snapshots and movies capture the fluoroscopic image or images overlaid with the dynamic roadmap.

To archive snapshots and movies, a PACS must be configured for use with Dynamic Coronary Roadmap. The snapshot or movie is automatically archived after you create it. For information about configuring a PACS, contact technical support.

Details of how to create snapshots and movies are provided with the procedures in this section.

4.3 Using Dynamic Coronary Roadmap

Use this procedure if you are not using an intravascular blood pressure measurement system (optional) with Dynamic Coronary Roadmap.

If you are using a compatible Philips intravascular blood pressure measurement system, use the following procedure instead: [Using Dynamic Coronary Roadmap with a Compatible Intravascular Blood Pressure Measurement System \(page 18\)](#).



CAUTION

Ensure that the following conditions are met during acquisition of the roadmap:

- *Ensure that you use the same catheter during live guidance that you used to create the roadmap.*
- *Ensure that the catheter tip is always visible.*
- *Instruct the patient to remain still.*
- *Do not move the stand or table.*
- *Acquire at least three contrast-enhanced heart cycles.*

NOTE

If there are other objects in the field of view, such as stitches, stents, or a pacemaker, the resulting roadmap may not be optimal.

NOTE

If similar anatomy is present in the region of interest (for example, parallel vessels), the resulting roadmap may not be suitable for live guidance due to unreliable spatial registration.

NOTE

The full coronary tree should be filled with contrast for at least three heart cycles. In case of chronic total occlusions, not all vessels might be filled with contrast agent. These vessels are not visible in the roadmap, or the roadmap itself might not be available.

NOTE

Depending on the anatomy, the quality of a roadmap may not be sufficient for device navigation. Always ensure that the selected roadmap is of sufficient quality by comparing the roadmap to the original angiogram.

NOTE

Autonomous patient movement or anatomy deformation due to device insertion may result in an incorrect overlay. If device navigation is hindered by an incorrect overlay, create a new roadmap. Alternatively, use the information from the live screen of the X-ray system and small puffs of contrast to assist with device navigation.

- 1 On the touch screen module, select a 2D coronary angiography procedure.
Guidance for using Dynamic Coronary Roadmap is displayed in the main view.



Figure 3 Guidance in the main view

For best results, use 15 fps.

- 2 Acquire a diagnostic coronary angiogram.

NOTE

It is the operator's responsibility to configure the injector. Refer to the Instructions for Use supplied with the injector.

To obtain an overview of the anatomy, you can acquire several angiograms. A roadmap is created and stored for each stand position and angulation.

As you acquire each angiogram, a roadmap is created and a preview of the roadmap is displayed in the main view along with its orientation and series number. Pictorials of all available roadmaps are displayed as you acquire more angiograms during the procedure.

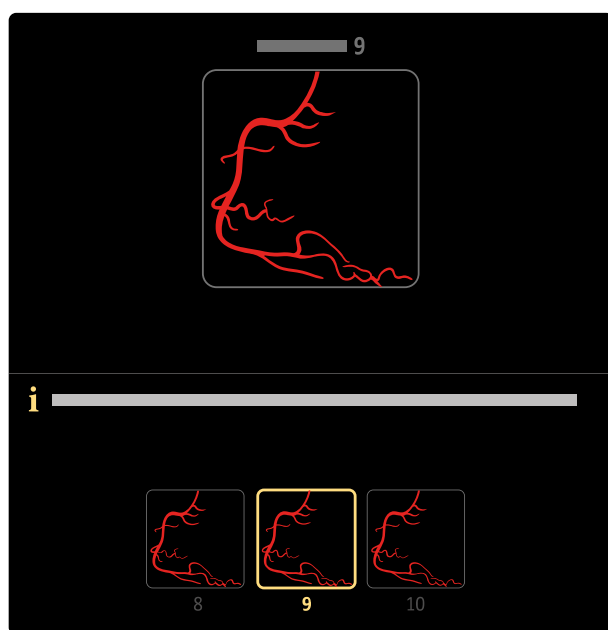


Figure 4 Overview of available roadmaps

The **Roadmap Options** screen is automatically displayed on the touch screen module. This screen provides the following functions:

- Select the roadmap to be used during live guidance.
- Lock the selected roadmap, if desired, to keep it selected if a new roadmap is created. If the current roadmap is not locked and you acquire a new angiogram during the procedure, the newly created roadmap is automatically selected.

- 3 If desired, select a different roadmap for live guidance using the left and right arrow buttons in the **Roadmap Options** screen.

The currently selected roadmap is indicated with a border in the main view.

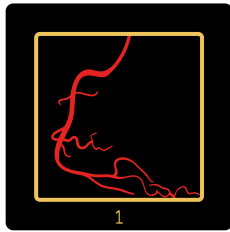


Figure 5 Selected roadmap

NOTE

You can also use the Roadmap Options screen on the touch screen module to select a different roadmap after live guidance has started, if desired.

- 4 If desired, lock the selected roadmap by tapping **Lock Roadmap** in the **Roadmap Options** screen.

When a roadmap is locked, a lock icon is displayed in the upper right corner of the roadmap preview, and the button on the touch screen module displays the text **Roadmap Locked**.



Figure 6 Locked roadmap

- a To unlock the roadmap, tap **Roadmap Locked** in the **Roadmap Options** screen.

- 5 Press the **Fluoroscopy** pedal and start live guidance of the device.
Fluoroscopy images are displayed in the main view, overlaid with the roadmap.

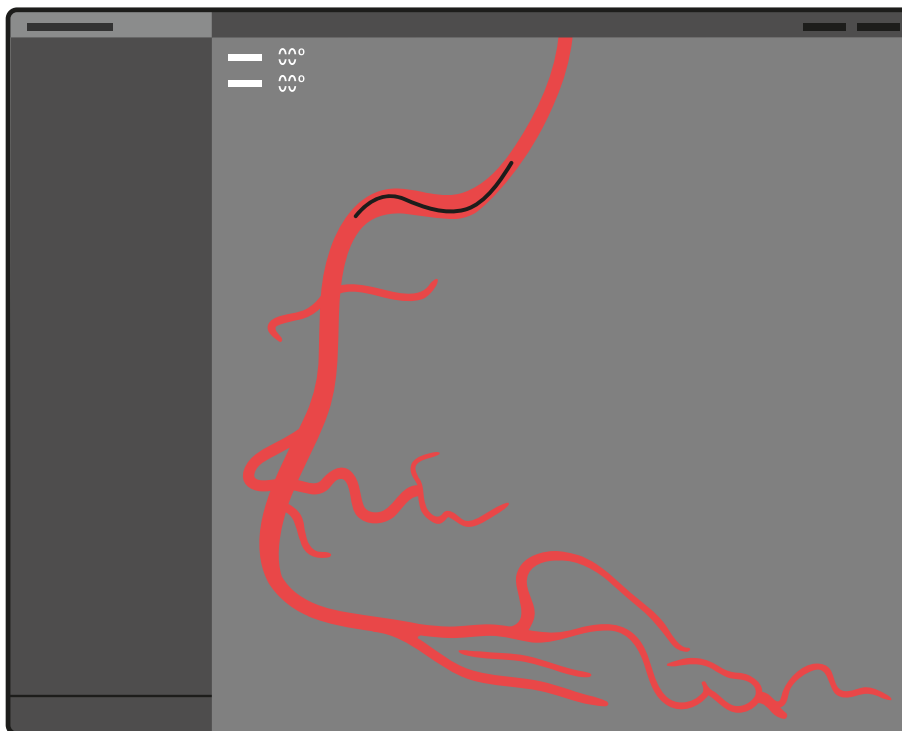


Figure 7 Dynamic coronary roadmap overlaid on live fluoroscopy images

NOTE

The location of the reference view, status indicators, and stand position information may vary depending on the configuration of your system.

- 6 Release the **Fluoroscopy** pedal to stop or pause live guidance.



The **Last Image Hold** is displayed in the main view.

- 7 To create a snapshot or movie of the main view, do the following:

- a On the touch screen module, do one of the following, depending on the configuration of your system:

- Tap **Tools**, and then tap **Next**.
- Tap the application selector.



- b Tap **Coronary Tools**.



- c To create a snapshot tap **Archive Snapshot**.

- d To create a movie, tap **Archive Movie**.

The movie consists of the last 20 seconds of the series.

NOTE

*The **Start Movie Record** function is not available for this task.*

Snapshots and movies are automatically archived on the default PACS that Dynamic Coronary Roadmap is configured to use.

- 8 You can continue with live guidance at the same orientation by pressing the **Fluoroscopy** pedal again, or you can move to a new orientation, acquire a new angiogram, and create a new roadmap.

NOTE

The roadmap for each selected orientation is stored for the duration of the procedure.

You can reuse a roadmap if you return to the same position at a later stage in the procedure:

- Within ± 2 degrees of the stand orientation.
- Within ± 30 mm of the table position.

Whenever an existing roadmap is available, guidance in the main view of Dynamic Coronary Roadmap provides information for positioning the stand or table to reuse the roadmap.

When a roadmap is available and the stand and table are in the correct position, the roadmap is displayed in red in the main view. You can perform live guidance using this roadmap by starting fluoroscopy.



Figure 8 Correct roadmap position is attained

When a roadmap is available but the stand or table is not in the correct position, the roadmap is displayed in gray, with a guidance message in the main view for positioning the stand or table.



Figure 9 Roadmap position is not yet attained

You can position the stand or table manually, or you can use automatic position control if it is available on the X-ray system. If automatic position control is available and enabled on the X-ray system, on-screen guidance for using this function to move the stand is provided. The on-screen guidance is displayed when the stand is not yet in the correct position to use a roadmap, but there is a roadmap within 10 degrees of the current stand orientation. To move the stand to the correct orientation for the roadmap, follow the on-screen guidance.

For more information about using automatic position control, refer to the Instructions for Use supplied with the X-ray system.

NOTE

Automatic position control may not be available if other software tools are used at the same time as Dynamic Coronary Roadmap.

NOTE

Dynamic Coronary Roadmap provides a user setting for optimal use in combination with the sequence option on the X-ray system, if available.

NOTE

All roadmaps are removed when the procedure ends.

4.4 Using Dynamic Coronary Roadmap with a Compatible Intravascular Blood Pressure Measurement System

NOTE

This feature is an option to the system. To use a compatible intravascular blood pressure management system with Dynamic Coronary Roadmap, additional licenses must be purchased.

Dynamic Coronary Roadmap can be connected to a compatible Philips intravascular blood pressure measurement system (optional) to measure intravascular blood pressure, using Pa (aortic pressure) and Pd (distal pressure) values. You can perform the following measurements:

- iFR (instant wave-Free Ratio) pullback measurement
- iFR spot measurement
- FFR (Fractional Flow Reserve) pressure measurement

If you are not using an intravascular blood pressure measurement system, use the following procedure instead: [Using Dynamic Coronary Roadmap \(page 14\)](#).

4.4.1 Connecting the Philips Volcano CORE Mobile System

If you are using the Philips Volcano CORE Mobile system (optional) with Dynamic Coronary Roadmap, you can connect it to the rear interface panel of a compatible Philips patient table. (For information about compatible equipment, contact Philips.)

The Philips Volcano CORE Mobile cable should be connected to the patient table by clinical staff each time that the Philips Volcano CORE Mobile system is to be used. Connect the cable to the connection port indicated in the following figure. Tools are not required to connect the cable.

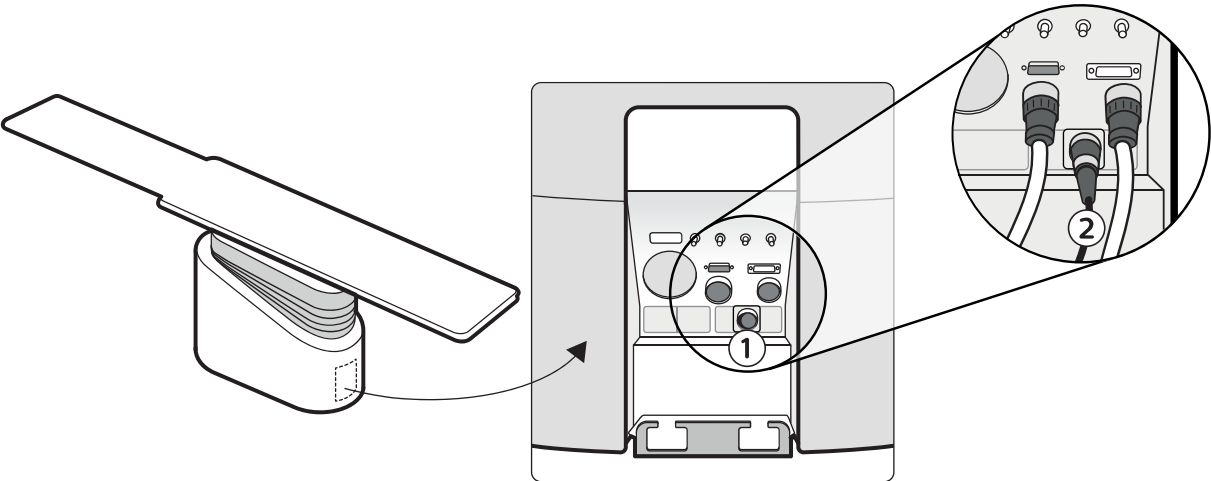


Figure 10 Connection for the Philips Volcano CORE Mobile system

Legend	
1	Connection port
2	Connection cable

The connection status of the Philips Volcano CORE Mobile system is indicated by a symbol in the lower-left corner of the Dynamic Coronary Roadmap window.

Connection Status	
	Philips intravascular blood pressure measurement system is connected
	Philips intravascular blood pressure measurement system is not connected

4.4.2 Performing an iFR Pullback Measurement

To prepare for this measurement, the following conditions are required:

- A dynamic coronary roadmap must be available.
- The pressure measurement guide wire must be normalized at ostium using the compatible Philips intravascular blood pressure measurement system.

After normalization, values from the compatible Philips intravascular blood pressure measurement system are displayed in the reference view of Dynamic Coronary Roadmap.

- 1 Start the pullback procedure on the compatible Philips intravascular blood pressure measurement system.

For information about using a compatible Philips intravascular blood pressure measurement system, refer to the Operator's Manuals supplied with the associated system.

- 2 Press the **Fluoroscopy** pedal to start live guidance.

The reference view displays pressure measurement information at the pressure sensor location, 3 cm proximal to the tip of the guide wire.

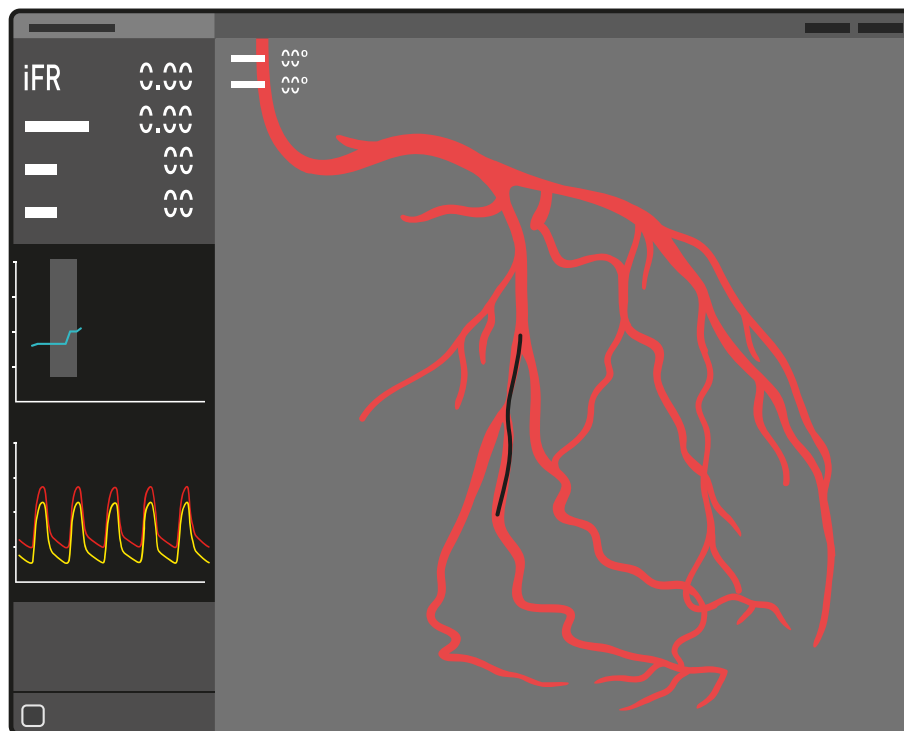


Figure 11 iFR pullback measurement

NOTE

The location of the reference view, status indicators, and stand position information may vary depending on the configuration of your system.

NOTE

During the live guidance phase of the iFR pullback, synchronization of the X-ray image with the intravascular blood pressure measurement is not guaranteed. Clinical decisions should be based on the iFR pullback review.

- 3 Release the **Fluoroscopy** pedal when the pullback procedure is completed.

The acquired series is displayed in the main view with the roadmap overlay. The series is co-registered with the iFR measurements in the reference view, allowing you to review the pullback using the touch screen module.

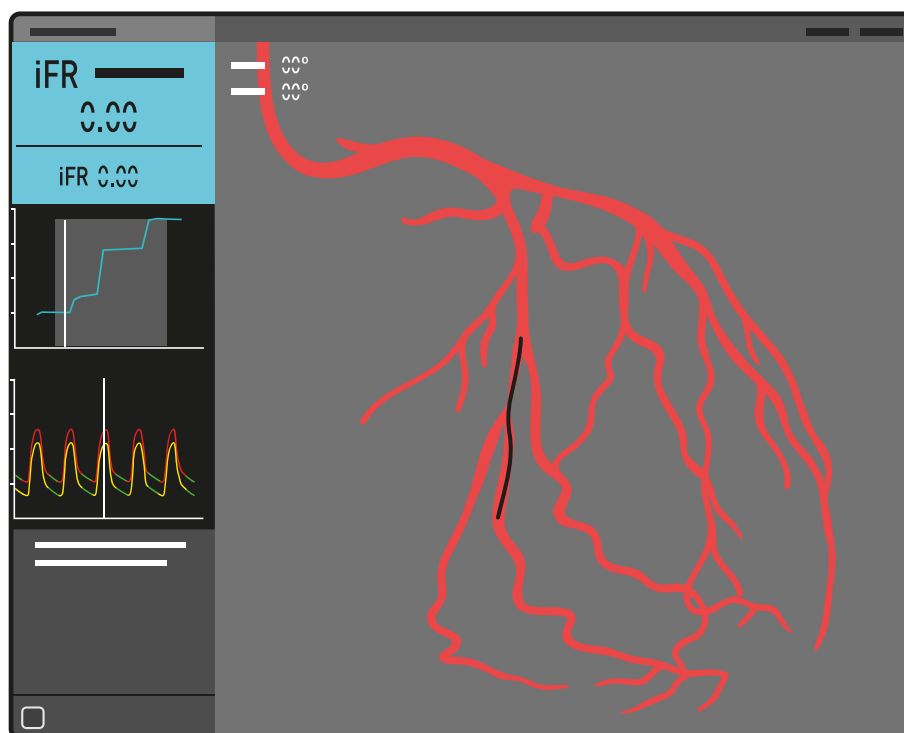


Figure 12 iFR pullback review

NOTE

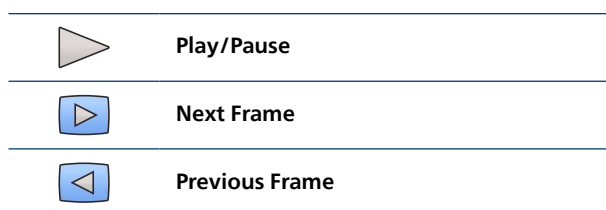
The location of the reference view, status indicators, and stand position information may vary depending on the configuration of your system.

- 4 To review the pullback, do the following:
- If the **Coronary Tools** are not displayed on the touch screen module, do one of the following (depending on the configuration of your system):

- Tap **Tools**, then tap **Next**, and then tap **Coronary Tools**.
- Tap the application selector, and then tap **Coronary Tools**.



- Use the review controls to review the series:



- To create a snapshot of the window, including the main view and the measurements in the reference view, tap **Archive Snapshot**.
- To create a movie of the window, including the main view and the measurements in the reference view, tap **Start Movie Record** to start recording. Tap the button again to stop recording.

The snapshot or movie is automatically archived on the default PACS that Dynamic Coronary Roadmap is configured to use.

4.4.3 Performing an iFR Spot Measurement

To prepare for this measurement, the following conditions are required:

- A dynamic coronary roadmap must be available.
- The pressure measurement guide wire must be normalized at ostium using the compatible Philips intravascular blood pressure measurement system.

After normalization, values from the compatible Philips intravascular blood pressure measurement system are displayed in the reference view of Dynamic Coronary Roadmap.

- 1 Perform the iFR spot measurement procedure on a compatible Philips intravascular blood pressure measurement system.

For information about using a compatible Philips intravascular blood pressure measurement system, refer to the Operator's Manuals supplied with the associated system.

- 2 During the iFR spot measurement procedure, press and release the **Fluoroscopy** pedal to perform co-registration.



When the measurement is complete, the main view displays the **Last Image Hold** co-registered with the iFR measurements in the reference view.



Figure 13 iFR spot measurement

NOTE

The location of the reference view, status indicators, and stand position information may vary depending on the configuration of your system.

- 3 To create a snapshot of the window, including the main view and the measurements in the reference view, do the following:

- a If the **Coronary Tools** are not displayed on the touch screen module, do one of the following (depending on the configuration of your system):



- Tap **Tools**, then tap **Next**, and then tap **Coronary Tools**.
- Tap the application selector, and then tap **Coronary Tools**.



- b Tap **Archive Snapshot**.

NOTE

The Start Movie Record function is not available for this task.

The snapshot is automatically archived on the default PACS that Dynamic Coronary Roadmap is configured to use.

4.4.4 Performing an FFR Pressure Measurement

To prepare for this measurement, the following conditions are required:

- A dynamic coronary roadmap must be available.
- The pressure measurement guide wire must be normalized at ostium using the compatible Philips intravascular blood pressure measurement system.

After normalization, values from the compatible Philips intravascular blood pressure measurement system are displayed in the reference view of Dynamic Coronary Roadmap.

- 1 Perform the FFR pressure measurement procedure on a compatible Philips intravascular blood pressure measurement system.
- 2 During the FFR pressure measurement procedure, press and release the **Fluoroscopy** pedal to perform co-registration.



When the measurement is complete, the main view displays the **Last Image Hold** co-registered with the FFR measurements in the reference view.



Figure 14 FFR pressure measurement

NOTE

The location of the reference view, status indicators, and stand position information may vary depending on the configuration of your system.

- 3 To create a snapshot of the window, including the main view and the measurements in the reference view, do the following:
 - a If the **Coronary Tools** are not displayed on the touch screen module, do one of the following (depending on the configuration of your system):
 - Tap **Tools**, then tap **Next**, and then tap **Coronary Tools**.
 - Tap the application selector, and then tap **Coronary Tools**.



- b Tap **Archive Snapshot**.

NOTE

The Start Movie Record function is not available for this task.

The snapshot is automatically archived on the default PACS that Dynamic Coronary Roadmap is configured to use.

4.5 Using a Mouse with Dynamic Coronary Roadmap

If a mouse is connected to the X-ray system, you can use the mouse with Dynamic Coronary Roadmap. Depending on the configuration of your system, the mouse may be automatically enabled when you open the **Coronary Tools** menu on the touch screen module, or you may have to enable it manually.

To enable the mouse manually, use the following procedure.

- 1** On the touch screen module, tap **Tools**, and then tap **Mouse**.
- 2** Tap **Coronary Tools** to enable the mouse, and then tap **Close**.

You can use the mouse to open the menus in the Dynamic Coronary Roadmap window. The menus provide access to technical support options and information about the system.

5 Maintenance

Due to the nature of this product, there are no maintenance tasks. For maintenance tasks related to the X-ray equipment, refer to the Instructions for Use supplied with the X-ray system.

5.1 Configuring User Preferences

You can configure user preferences to set the default behavior of automatic position control (APC) in Dynamic Coronary Roadmap.

You can choose between default APC behavior or sequence APC behavior. To change this setting, do the following:

- 1 In the **System** menu of Dynamic Coronary Roadmap, click **Philips SupportConnect**.

NOTE

If you attempt to start Philips SupportConnect while a DICOM transfer task is in progress, an on-screen message is displayed, recommending that you wait for the transfer to finish before starting Philips SupportConnect. If you start Philips SupportConnect before the transfer finishes, any snapshots or movies that are not yet transferred will be lost. Click Close (X) in the upper-right corner of the message box, wait for the transfer to finish, and then start Philips SupportConnect.

- 2 In the **Customization** window, click **User Preferences**.
- 3 In the **Dynamic Coronary Roadmap** section of the **User Preferences** window, select either automatic programming (default APC behavior) or sequence usage.
- 4 Click **Apply** to confirm your changes.

5.1.1 Configuring a PACS for Snapshots and Movies

To archive snapshots and movies, a PACS must be configured for use with Dynamic Coronary Roadmap.

Snapshots and movies are automatically archived to the configured PACS after they are created. For more information about configuring a PACS, contact technical support.

5.2 Saving a Log File for Technical Support

When a problem arises with the function of the software medical device, you can assist technical support by generating a log file. The log file contains details of the system configuration, software versions, screenshots, and error logs.

NOTE

The log file may contain personal data. It is your responsibility to stay within your institution's policy regarding disclosure of medical information, and in accordance with any privacy laws in force in the jurisdictions in which the product is being used.

- When a service engineer requests that you create a log file, click **Save Log File for Technical Support** on the **System** menu.

5.3 Starting Remote Assistance

Remote assistance allows a service engineer to observe and assist with problems with the software medical device. Remote assistance is only available during service mode.

Clinical application is not allowed during maintenance and service.

NOTE

During remote assistance, personal data is not de-identified. It is your responsibility to ensure patient privacy is maintained during remote assistance.

- 1** Request remote assistance from a service engineer by calling your service access telephone number.
The service engineer starts the remote assistance tool and sends a connection request.
- 2** If you are satisfied that patient privacy will not be compromised, accept the connection request.
The service engineer can observe and assist with your problem, and can control functions on the software medical device. If you do not accept the remote assistance connection request within 30 seconds, the request is automatically refused.
- 3** To terminate remote assistance, click the remote assistance status indicator
The service engineer may also terminate remote assistance.

5.4 Disposing of Dynamic Coronary Roadmap

Dynamic Coronary Roadmap may contain personal data, which presents a security risk. Personal data should be handled in a secure way.

Contact Philips for information about how to dispose of Dynamic Coronary Roadmap securely. See [Contacting Philips \(page 8\)](#).

6 Security

6.1 Customer Role in the Product Security Partnership

Philips recognizes that the security of its products is an important part of your facility's in-depth security strategy. However, these benefits can only be realized if you implement a comprehensive, multi-layered strategy (including policies, processes, and technologies) to protect information and systems from external and internal threats.

Following industry-standard practice, your strategy should address physical security, operational security, procedural security, risk management, security policies, and contingency planning. The practical implementation of technical security elements varies by site and may employ a number of technologies, including firewalls, virus-scanning software, and authentication technologies.

As with any computer-based system, protection must be provided such that firewalls or other security devices are in place between the medical system and any externally accessible systems. The USA Veterans Administration has developed a widely used Medical Device Isolation Architecture for this purpose. Such perimeter and network defenses are essential elements in a comprehensive medical device security strategy.

The latest information on security and privacy, including recommended customer actions, can be found on the following website:

www.philips.com/productsecurity

NOTE

You should check the system's published cyber security status regularly on this website.

6.1.1 Risks Related to Security

To ensure the confidentiality, integrity, and availability of the device and related data, you should assess the risks to security based on the following recommendations.

- Implement network and physical access controls to limit the likelihood of compromise. For more information, see [Customer Role in the Product Security Partnership \(page 28\)](#).
- Monitor the product security recommendations issued by Philips on a regular basis. For more information, see [Malware Protection \(page 29\)](#).

The assessment should be repeated whenever changes are made to the network. Such changes include:

- Changes in the network configuration
- Connection of additional items to the network
- Disconnection of items from the network
- Updates or upgrades to items that are connected to the network

6.1.2 Detecting Security Failures

Dynamic Coronary Roadmap is designed to handle errors, including security failures, and restricts user access to the application level only. The system provides logging capabilities for local and remote services that support diagnostics and forensics.

Security failures arising from user actions display error messages for the user and create audit events according to the IHE ATNA integration profile.

Network communication failures are audited. An error message is displayed for the user when user interaction is required.

System failures are handled depending on the nature and severity of the failure and may result in changes to the workflow, error messages, logging, or audit events. For example, software that is not on the whitelist is not executed and the failure is logged.

A number of security features have been implemented in this product. It is recommended to contact technical support to activate these features, in cooperation with the IT specialist of the hospital. These features are described below.

Encryption of Personal Data

When personal data is stored on the system, this feature ensures that the media cannot be misused when removed from the system or site.

Secure DICOM Transfer

When medical images or data are transmitted over a network, this feature ensures that the data is not modified by intruders during transmission, as well as ensuring that the data cannot be read if it is intercepted and displayed.

This feature can be switched on or off for each network node, if required.

Audit Trail

Any user action involving personal data is logged to allow analysis as to whether any hostile action has been performed on the personal data.

Network Time Synchronization

This function ensures that every device on the network uses the same clock so that all relevant user actions and data transmissions, including audit trail actions, can be checked in chronological order.

This function can be configured by the service engineer during installation.

6.2 Malware Protection

Philips systematically analyzes sources of information related to cyber security vulnerabilities to assess the equipment's cyber security risk. To ensure the proper functioning of the medical device, Philips may recommend specific customer or service actions, or issue service recommendations to update, alter, or even replace the equipment's protection mechanisms.

The latest information, including the Product Security Policy Statement and recommended customer actions, can be found on the following website:

www.philips.com/productsecurity

NOTE

You should regularly check the published equipment's cyber security status on the website mentioned above.

Despite preventive measures already implemented, a remote possibility remains that the equipment may become infected with malware. When malware is detected, or when you notice that unfamiliar behavior or degraded performance occurs repeatedly, including after switched off and on again, you should contact technical support for an inspection. When the inspection confirms the infection, be sure to take measures to contain and remove the source of infection. Technical support will reinstall the equipment's software to bring the equipment back into specification. Technical support can also assist in accessing the equipment's event log, which may provide information useful for the investigation.

6.2.1 Security Updates

This equipment incorporates protection mechanisms against the intrusion of malware such as viruses. Without proper cyber security maintenance, the effectiveness of these provisions may degrade over time, since malware is continuously altered to target newly discovered vulnerabilities.

The systematic analysis on cyber security vulnerabilities includes an assessment on the applicability and need for applying security updates taking into account mitigating circumstances in the intended use and design of this equipment.

Security updates alter the equipment's design and thus require proper validation and approval by Philips. Security updates are deployed by the Philips Service organization and are only to be installed by authorized service engineers according to Philips maintenance procedures for medical devices.

The latest information, including recommended customer actions, can be found on the following website:

www.philips.com/productsecurity

6.2.2 Whitelist Protection

Whitelist protection software is installed on this equipment. The whitelist identifies all trusted software, which is allowed to execute on the equipment.

The protection software prohibits the execution of untrusted software, thus effectively blocking malware before damage is done. Instead of relying on frequent updates, as for antivirus software, it offers proactive protection against a wide spectrum of malware and malware alterations.

Since only known trusted software is allowed to run, no regular updates are required.

7 Glossary

Abbreviation or Term	Definition
balloon markers	A radiolucent particle on the balloon (usually at the tips) to give an indication of the size and location of the device under X-ray.
cardiovascular	Conditions that involve narrowed or blocked blood vessels that can lead to a heart attack, chest pain (angina), or a stroke.
cath lab	Catheterization laboratory.
co-register	Images or data from different sources integrated into one image, indicative of a certain point (for example, time).
contrast-enhanced heart cycles	Coronary artery vessels filled with contrast medium over one heart beat (and can be seen or captured angiographically).
coronary arteries	Arteries that supply the heart.
Coronary Tools	A dedicated coronary image guidance workstation.
coronary vessels	Vessels that supply the heart.
Dynamic Coronary Roadmap	A software medical device that is intended to provide a dynamic angiographic roadmap of coronary arteries in real time.
enhanced stent	The final processed and integrated stent images.
FFR/iFR roadmap	Relating to the intravascular blood pressure measurement to its anatomical location through the dynamic coronary roadmap.
LCA	Left coronary artery.
pacemaker	A device for stimulating the heart muscle and regulating its contractions.
PCI	Percutaneous coronary intervention: A non-surgical procedure that uses a catheter (a thin flexible tube) to place a small structure called a stent to open up blood vessels in the heart that have been narrowed by plaque buildup, a condition known as atherosclerosis.
RCA	Right coronary artery.
stent	A metal or plastic tube inserted into the lumen of an anatomic vessel or duct to keep the passageway open.
stent deployment	Readying of a system by disseminating a captured device (stent).
StentBoost	An option that provides optimized, processed and enhanced visualization of stents. Note: This applies in the context of the StentBoost Live product only.
StentBoost Live	A software medical device that is intended to provide enhanced visualization of stents. The images are processed in real time.
StentBoost Subtract	An option that provides optimized and enhanced visualization of stents in relation to coronary vessels. Note: this applies in the context of the StentBoost Live product only.
stiches	Surgical metal wire that is used to close or tie up a surgical incision.

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This medical device conforms with the applicable requirements set out by the European Union, as demonstrated in the Declaration of Conformity.

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